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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,212	10/30/2003	David R. Hennings	NSL-501	2780

34313 7590 02/12/2007
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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/699,212

Applicant(s)

HENNINGS ET AL.

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 17, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-23 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-23, and 25-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant argues that Sinofsky "is totally irrelevant art" as the purpose of the device of Sinofsky is to improve the functionality of blood vessels. The examiner must respectfully disagree. The disclosure of Sinofsky clearly states that the invention "relates to laser and catheters and optical fiber systems for generating and transmitting energy to a surgical site in a living body for the purposes of tissue removal or repair" as such it is the examiner's view that this purpose is sufficiently close to the known object in the art of "destroying the endothelial cells" (see the originally filed disclosure, page 4, line 13) to render Sinofsky pertinent prior art. However, even if this were not the case, Dew et al expressly teach, at column 2, lines 18-³⁰₁, that for a given tissue type, the laser light may propagate through the tissue, substantially unattenuated, or may be almost entirely absorbed. Of course, the extent to which the tissue is heated and ultimately destroyed, depends on the extent to which it absorbs the optical energy. It is generally preferred that the laser light be essentially transmissive in tissues which are desired not to be affected, and absorbed by the tissues which are to be affected. For example, when using lasers in fields which are wet with blood or water, it is desired that the optical energy not be absorbed by the water or blood, thereby permitting the laser energy to be directed specifically to the tissues desired to be affected." Thus clearly Dew et al teach one of ordinary skill in the art, who for the instant invention would be a dermatological surgeon, that the laser energy should be adjusted so as to interact preferentially with the tissue (i.e. the blood vessel wall, as expressly stated by Goldman et al) desired to be affected.

Applicant then posits that in the real world those attempting to use lasers "to accomplish

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the purpose of Goldman” deliberately chose not to use applicant’s wavelengths. The examiner must respectfully disagree. Firstly, it is noted that the three articles submitted by applicant’s do not constitute a statistically significant sample of all the publications dealing with laser treatment of varicose veins and as such cannot be the basis for a claim such as made by applicant.

Secondly, the “purpose of Goldman” is to heat the vessel wall (see, for example column 9, line 13). The purposes of the articles submitted by applicant is to heat the blood in the vessel. And, as clearly taught by Dew et al and set forth above, this is achieved by employing wavelengths that are absorbed by the tissue that is desired to be heated.

Applicant also disputes the combinability of the Roth et al and Makower et al. However, applicant’s scenario for combining these references disregards the underlying teachings of the references and seeks to bodily incorporate them in a way in which, one of ordinary skill in the art would never do. This scenario, however, does nothing to diminish the propriety of the actual combination applied to the claims by the examiner. Further, though Makower et al do not expressly teach the suppression of the fundamental wavelength of the Nd:YAG, to produce radiation in the claimed range, there is no need for Makower et al to do so, as this is already expressly taught by Dew et al. Thus the absence of this teaching in Makower et al is of little moment.

Claims 1, 2, 6, 7, 25, 35-38, 40, 41, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al (‘084) in combination with Sinofsky and Dew et al. Goldman et al (‘084) teach a method as claimed, but do not specify a wavelength. Sinofsky teaches the notorious nature of the high absorption of infrared wavelengths in the art. Dew et al teach the desirability of using 1.3 micron radiation to treat tissue. It would have been obvious to

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the artisan of ordinary skill to employ the wavelength of Dew et al in the method of Goldman et al ('084), since Goldman et al ('084) teach no particular wavelength, and since the wavelength of Dew can destroy (denature) the proteins, but allow near normal tissue to take its place, and since this wavelength is highly absorbed by tissue and water, as taught by Sinofsky, thus producing a method such as claimed.

Claims 3-5, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Roth et al. Roth et al teach employing pull back rate as claimed, noting that the desired rate is dependent on the laser energy. It would have been obvious to the artisan of ordinary skill to employ a pull back as claimed, since these are known in the art and provide no unexpected result and to initiate pulling prior to energy application, since the problem of tissue adhesion is notorious in the art official notice of which is hereby taken, thus producing a method such as claimed.

Claims 8 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Conn et al. Conn et al teach a diffusing tip as claimed, it would have been obvious to the artisan of ordinary skill to employ a tip as taught by Conn et al, since this would provide a uniform distribution of light and would prevent over or under treatment of tissue different areas of tissue, while thus producing a method such as claimed.

Claim 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7 and 25 above, and further in view of Makower et al. Makower et al teach controlling the heating of tissue using

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infrared sensing. It would have been obvious to the artisan of ordinary skill to employ the temperature sensor of Makower et al in the method of Goldman et al ('084) since these are equivalents, as taught by Makower et al, thus producing a method such as claimed.

Claim 14-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Roth et al and Dew et al. Makower et al teach a device as claimed except the particular laser wavelength and the pull back mechanism. Dew et al teach a wavelength as claimed for treating tissue. Roth et al teach a pull back mechanism providing the claimed rate. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the device of Makower et al, since Makower et al teach the use of an Nd:YAG laser, which necessarily produces this radiation, as taught by Dew et al and to employ the pull back mechanism of Roth et al, since this enables uniform treatment along the surface, as taught by Roth et al, thus producing a device such as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Dew et al and Roth as applied to claims 14-17 and 20-23 above, and further in view of Conn et al. Conn et al teach a diffusing tip on an introducer for a fiber. It would have been obvious to the artisan of ordinary skill to include the diffuser of Conn et al in the device of Makower et al, since this reduces problems due to breakage, as taught by Conn et al, thus producing a device such as claimed.

Applicant's arguments filed November 17, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
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GROUP 330